

## **REMARKS**

The specification is amended herein to refer to the appropriate sequence identifiers. Support for the amendment of page 6 can be found in Fig. 2 and on pages 23-34.

Claims 27 and 44 are canceled herein without prejudice to renewal. Claims 25, 28, and 45 are amended herein without prejudice. Support for the amendment of claims 25 and 28 can be found in the specification at page 14, lines 24-32. Claim 45 has been amended to correct form.

No new matter is added. Reconsideration of the subject application is respectfully requested. The Examiner is thanked for the further consideration given to this application.

### **Restriction Requirement**

Applicants note the restriction requirement has been made final and reserve the right to petition the restriction requirement.

### **Sequence compliance**

A paper and an electronic copy of a sequence listing have been submitted to Mail Stop Sequence, along with a Statement of Compliance. For the Examiner's convenience, a paper copy of the Sequence Listing and a copy of the Statement in Compliance, as submitted to Mail Stop Sequence, are enclosed herewith. In addition, the specification is amended herein to refer to the appropriate sequence identifiers. Applicants believe that following entry of this amendment the specification will be in compliance with 37 C.F.R. § 1.821-25.

### **Specification**

The Brief Description of the Drawings is amended herein as requested by the Examiner, rendering the objection moot.

### **Rejection under 35 U.S.C. §112 second paragraph**

Claim 25 is rejected as allegedly being unclear. Applicants respectfully disagree with these rejections.

Solely to advance prosecution, claim 25 has been amended to specify only antigenic material from an attenuated live mutant bacterium with a diluent or carrier. This amendment is made without prejudice to renewal.

Amended claim 25 also specifies that the fur promoter has been mutated such that levels of expression from the modified fur promoter is at least equal to those obtained using the native fur in the presence of low levels of ferric ions. Additionally the amended claim specifies that it is the fur promoter which is modified by insertion, deletion and/or substitution. Regarding the immunoprotective abilities of the modified bacterium, applicants submit that it is the present application that describes the immunoprotective abilities, and that the modification of the fur promoter such that the bacterium produces lower levels of fur means that there is enhanced expression of other membrane proteins which are immunogenic.

Claim 45 is rejected as allegedly being indefinite. Applicants respectfully disagree. However, solely to advance prosecution, claim 45 specifies "treating a subject to stimulate an immune response against the mutant bacterium," thereby rendering the rejection moot. Applicants respectfully submit that there is no need to include in the claim the "name" of a disease or ailment, as the claim is clearly amended to indicate that an immune response in the subject towards the bacterium is stimulated.

### **35 U.S.C. § 112 first paragraph**

Original claims 25-27 and 45 were rejected as allegedly not being enabled by the specification. Applicants respectfully disagree with this rejection as might be applied to the claims as amended.

The amended claims specify a mutant bacterium with a mutation in the fur gene promoter. Applicants respectfully submit that the application gives guidance as to how to make and use the claimed mutant bacteria, such as at page 14-36 of the specification. It is respectfully suggested that further experimental results, such as the *in vivo* results mentioned in the Office action, are not required to demonstrate enablement.

However, the application does contain certain experimental results which do show that a decrease in fur expression increases expression of certain fur regulated proteins, see the specification at page 31, lines 13-30. Additionally, regarding bacteria which are other than *Neisseria meningitides*, the specification describes bacteria which are known to have a fur gene or homologue, such as at page 4, paragraph 3. It is not a requirement for enablement to give actual examples and experimental results for each and every one of the bacteria claimed. Regarding the assertion that the specification only gives prophetic examples of how to make the claimed mutants, applicants respectfully refer to the examples presented in the specification, such as at pages 14-15 and at pages 29-31.

With regard to the assertion in the Office action that the specification is not enabling for modification of the fur gene (see page 9 of the Office action), applicants respectfully disagree. Applicants note that such modifications are described in the specification, for example at page 31, and the specification is fully enabling. In addition, to advance prosecution, the amended claims specify certain modifications of the fur gene promoter.

Hence, the applicants submit that the pending claims are fully enabled by the specification. Reconsideration and withdrawal of the rejections are respectfully requested.

### **Rejections under 35 U.S.C. § 102(b)**

Claims 25-27 and 45 were rejected as anticipated by WO 94/05326 (Allan et al.). Applicants respectfully disagree with this rejection as applied to the claims as amended.

Allan et al. mentions "mutants defective in fur metabolism" (page 12, lines 10-12) and describes making fur mutants by transposon insertion into the fur gene (at pages 21-23). Allan et al. also describes how to identify these fur mutants (at pages 24-25, lines 25-27). The claims as amended specify certain modifications of the fur gene, namely modifications of the fur promoter. Allan et al. does not describe these modifications of the fur promoter. Moreover, given the disclosure of Allan et al., one would not be motivated to make modifications of the fur promoter. Hence applicants submit that Allan et al. does not anticipate, nor render obvious, claims 25-27 and 45.

Reconsideration and withdrawal of the rejections is respectfully requested.

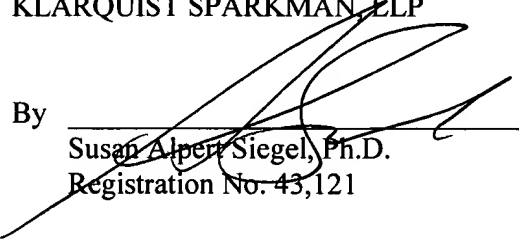
### Conclusion

Applicants believe that all of the outstanding rejections have been addressed, and that claims 25-27 and 45 are in condition for allowance. If any minor matters remain to be discussed before a Notice of Allowance is issued, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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